



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

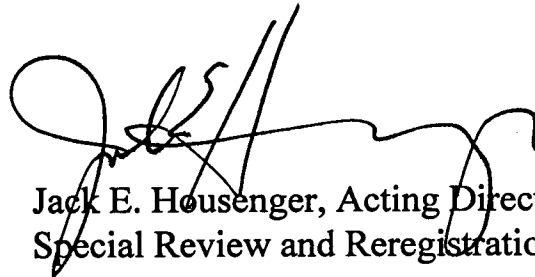
The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

A handwritten signature in black ink, appearing to read 'J. Housenger', is written over the typed name and title.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



Office of Prevention, Pesticides
and
Toxic Substances

November 1, 1999

Memorandum

Subject: **Phosalone** (PC Code: 097701; DP Barcode: D260580). Acute and Chronic
(Non-cancer) Dietary Exposure and Risk Analyses for Phosalone

From: Kristina A. EL-Attar, Environmental Protection Specialist
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Reregistration Branch 1
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To: William J. Hazel, Risk Assessor
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The following document, prepared as part of the Preliminary Human Health Risk Assessment, estimates the acute and chronic (non-cancer) dietary exposure and risk to phosalone from select imported commodities. The Dietary Exposure Evaluation Model (DEEMTM) was used to evaluate exposures and risks using anticipated residues (ARs) contained in a memorandum entitled "Phosalone (PC code: 097701; DP Barcode: D260579): Anticipated Residue Estimates for Purposes of Dietary Exposure Refinement for Select Import commodities" (K. EL-Attar, 11/01/99).

Background

Phosalone [*O,O*-diethyl S-[(6-chloro-2-oxobenzoxazolin-3-yl)methyl] phosphorodithioate] is an organophosphate insecticide and acaricide for which U.S. registrations were voluntarily withdrawn in 1989 by the registrant, Rhône-Poulenc Ag Company (RPAC). The Agency proposed revoking tolerances for pesticides with no active registrations, including tolerances for residues of phosalone in/on plant and animal commodities (63 *FR* 3057, 1/21/98). However, in response to this proposal, RPAC requested that the Agency not revoke tolerances for phosalone residues in/on almonds, grapes, pome fruits (apples and pears), and stone fruits (apricots, cherries, peaches, and plums) so that these commodities could continue to be imported legally by the U.S. In the Final Rule published in the Federal Register of 10/26/98 (corrected 1/25/99), the Agency determined to maintain existing tolerances for residues of phosalone in/on the specified commodities while revoking the remaining phosalone tolerances under 40 CFR §180.263 and §186.4800.

Executive Summary

Acute probabilistic dietary exposure and risk assessments were conducted using separate toxicological endpoints for the “General U.S. Population Including All Subgroups,” and “Females 13+ Years.” Both acute risk assessments were below HED’s level of concern with <1% of the acute population adjusted dose (aPAD) shown for the “General U.S. Population Including All Subgroups” and “Females 13+ Years” at the 99.9th percentile of exposure. The analyses were based almost entirely on monitoring data obtained from the FDA Surveillance Monitoring Program (1992-1998).

Chronic (non-cancer) dietary exposure and risk were below HED’s level of concern with <1% of the chronic population adjusted dose (cPAD) reported for all subgroups. Again, the analysis was based almost entirely on FDA Surveillance Monitoring Data (1992-1998).

A quantitative cancer risk assessment was not performed for phosalone since the pesticide is considered “not likely” to be a human carcinogen.

RPAC submitted acute and chronic dietary analyses generated by Novigen Sciences, Inc. Although these analyses will not be reviewed in detail, the exposures and risks reported by the registrant were comparable to those generated by the Agency.

DETAILED CONSIDERATIONS

Toxicological Information

Table 1 summarizes the toxicological endpoints selected for phosalone. The aPADs and cPAD presented in this table were used in assessing the acute and chronic (non-cancer) dietary exposure and risk to the pesticide.

Table 1. Summary of Toxicological Endpoints for Use in Acute and Chronic Dietary Risk Assessment

EXPOSURE	DOSE (mg/kg/day)	ENDPOINT	STUDY
Acute Dietary (General population including infants and children)	LOAEL = 10	Plasma ChE inhibition	Acute neurotoxicity in rats
	UF =300, FQPA=1 Acute PAD= Acute RfD = 0.03 mg/kg /day		
Acute Dietary (Females 13+ years)	Developmental NOAEL = 1	Post-implantation loss	Developmental toxicity in rabbits
	UF =100 FQPA=1 Acute PAD=Acute RfD= 0.01 mg/kg /day		
Chronic Dietary	NOAEL = 0.2	Plasma and RBC ChE inhibition (both sexes), decreased testicular weight and lesions	2-Year Rat Study
	UF =100 FQPA=1 Chronic PAD=Chronic RfD = 0.002 mg/kg/day		

LOAEL= Lowest Observable Adverse Effects Level, NOAEL = No Observable Adverse Effects Level, UF= Uncertainty Factor, FQPA= Food Quality Protection Act Safety Factor, PAD= Population Adjusted dose; RfD=Reference Dose

Note: The information presented in this table was adapted from a memorandum submitted to the Hazard Identification Assessment Review Committee (HIARC) for consideration in endpoint selection (Kit Farwell, 08/12/99).

Residue Information

The acute and chronic (non-cancer) exposure and risk to phosalone on select imported commodities were assessed using the anticipated residue values in Table 2, which were reprinted from a memorandum entitled “Phosalone (PC code: 097701; DP Barcode: D260579). Anticipated Residue Estimates for Purposes of Dietary Exposure Refinement for Select Import Commodities” (K. EL-Attar, 11/01/99). Residue Distribution Files (RDFs) were used to express phosalone residues for “partially blended” and “not blended” commodities; an average residue value (point estimate) was used for “blended” commodities. This treatment of the anticipated residues within DEEMTM was chosen because of the largely non-detectable nature of the residues within the database and the insufficient number of samples analyzed to decomposite residues for the “not blended” commodities (HED SOP 99.6, 08/20/99).

To adjust for ARs on processed commodities/food forms, adjustment factor #1 was utilized in DEEM™. The program default concentration/reduction values were retained in most instances. A reduction factor of 0.3 was applied to canned apple products on the basis of a registrant-submitted study that suggested a decrease in phosalone residue in/on the processed commodity. This processing factor was translated to canned peaches, pears, and plums by assuming similar commercial processes for these commodities. The DEEM™ default value of 1.3 was removed for “Apples-juice/cider” since a RDF was constructed from residue information specific to apple juice. The processing factor for “Apples-juice-concentrate” was changed from 3.9 to 3.0 in order to maintain the appropriate concentration ratio with “Apples-juice/cider.”

One hundred percent crop treated (CT) was assumed for all commodities resulting in a value of one for adjustment factor #2. This assumption of 100% CT was viewed as being conservative for the dietary exposure to phosalone since the market share of the pesticide was not considered in the production of the exporting countries.

Table 2. Summary of ARs for Phosalone in/on Imported Fruits and Fruit Commodities

Crop	Commodity	Chronic Anticipated Residue, ppm ^a	Residue Distribution for Acute Anticipated Residue ^b
Almonds ^c	nutmeat	3.00e-02	0 (1,499,997), 0.025(2), 0.048
Apples ^d	fresh + dried	1.30e-04	0 (6,153), 0.0015 (83), 0.140, 0.200, 0.087, 0.060, 0.200
	juice	2.10e-04	0 (455), 0.0015 (73)
Apricots ^d	fresh	1.40e-05	0 (15,069), 0.0015 (58), 0.130
Cherries (Sweet & Tart)	fresh	1.60e-02	0 (2,341), 0.59, 0.38, 0.23, 0.35, 0.42, 0.25, 6.00 (6)
Grapes ^d	fresh + juice + wine	6.70e-05	0 (2,271), 0.0015 (107)
	raisins	5.80e-05	0 (8,185), 0.0015 (36), 0.420
Peaches ^d	fresh	1.80e-06	0 (117,941), 0.0015 (58), 0.130
Pears ^d	fresh	9.00e-07	0 (143,247), 0.0015 (86)
Plums ^d	fresh	6.20e-06	0 (34,647), 0.0015 (58), 0.130

^a Values in this column incorporate the percent imported from countries with phosalone registrations.

^b Residue values in this column also reflect the percent imported from countries with phosalone registrations. The frequency of the residue value is indicated in parentheses.

^c LOD (limit of detection) equivalent to LOQ (limit of quantitation) = 0.05 ppm; ½ LOD = 0.025 ppm. ½ LOD was used to represent almonds with non-detectable residues less than the LOD.

^d LOD (limit of detection) equivalent to LOQ (limit of quantitation) = 0.003 ppm; ½ LOD = 0.0015 ppm. ½ LOD was used to represent non-detectable residues less than the LOD for the indicated crops.

Consumption Data

HED conducts dietary risk assessments using the Dietary Exposure Evaluation Model (DEEM™), which incorporates consumption data generated in USDA’s Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-1992. For acute probabilistic dietary risk assessments, the entire distribution of residues are used to obtain a distribution of exposures in mg/kg/day. For chronic

dietary risk assessments, a three-day average of consumption for each sub-population is combined with residues in commodities to determine average exposure in mg/kg/day.

Results/Discussion

Acute and chronic (non-cancer) dietary exposure and risk estimates were based primarily on FDA monitoring data; relatively few AR estimates were derived from field trial studies. The assessments included reduction of residues during processing and the percent of commodity imported by the U.S. from countries with phosalone registrations. The analyses were considered highly refined for dietary exposure and risk to phosalone.

Two acute probabilistic dietary exposure and risk analyses for phosalone were conducted in order to account for separate toxicological endpoints—one for the “General U.S. Population Including All Subgroups” (aPAD=0.03 mg/kg/day) and one for “Females 13+ Years” (aPAD=0.01 mg/kg/day). In both assessments, <1% of the aPAD was indicated for population subgroups at the 99.9th percentile of exposure. The results of the analyses did not exceed HED’s level of concern. Table 3 summarizes the results of the acute assessments.

The results of the chronic (non-cancer) dietary assessment showed <1% of the cPAD for all population subgroups (Table 3). The results of the chronic (non-cancer) dietary analysis did not exceed HED’s level of concern.

Table 3. Summary of Phosalone Acute & Chronic (Non-cancer) Dietary Exposure and Risk Estimates^a

Population Subgroup	Acute Assessment (99.9th %-ile of Exposure)				Chronic Assessment	
	General U.S. Population Including All Subgroups		Females 13+			
	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.000049	0.16	N/A	N/A	0.000001	0.0
All Infants (<1 yr)	0.000084	0.28	N/A	N/A	0.000001	0.1
Children (1-6 yrs)	0.000221	0.74	N/A	N/A	0.000002	0.1
Children (7-12 yrs)	0.000132	0.44	N/A	N/A	0.000001	0.0
Females (13-50 yrs)	0.000016	0.05	0.000017	0.17	0.000000	0.0
Males (13-19 yrs)	0.000014	0.05	N/A	N/A	0.000000	0.0
Males (20+ yrs)	0.000017	0.06	N/A	N/A	0.000000	0.0

^a The acute population adjusted dose (aPAD) is 0.03 mg/kg/day for the “General U.S. Including All Subgroups” and 0.01 mg/kg/day for “Females 13+ years.” The chronic population adjusted dose (cPAD) is 0.002 mg/kg/day.

List of Attachments

- Attachment 1. Residue Distribution Files for Select Import Commodities
- Attachment 2. Acute Dietary Analysis using Endpoint for General U.S. Population
(including all subgroups)
- Attachment 3. Acute Dietary Analysis using Endpoint for Females 13+ Years
- Attachment 4. Chronic (Non-cancer) Dietary Analysis

cc: **Deanna P. Scher**, Review Manager, Special Review and Reregistration Division, Office of Pesticide Programs;
William J. Hazel, Risk Assessor, Health Effects Division, Office of Pesticide Programs;
Kristina A. EL-Attar, Environmental Protection Specialist, Health Effects Division, Office of Pesticide
Programs

Attachment 1. Residue Distribution Files for Select Import Commodities

Almonds, nutmeat
TOTALNZ=1
TOTALZ=1499997
TOTALFREQ=1
2, 0.025
0.048

Apples, fresh+dried
TOTALNZ=5
TOTALZ=6153
TOTALFREQ=1
83, 0.0015
0.140
0.200
0.087
0.60
0.200

Apple, juice
TOTALZ=455
TOTALFREQ=1

73, 0.0015

Apricots, fresh
TOTALNZ=1
TOTALZ=15069
TOTALFREQ=1
58, 0.0015
0.130

Cherries (sweet& tart), fresh
TOTALNZ=6
TOTALZ=2341
TOTALFREQ=1
6, 6.00
0.59
0.38
0.23
0.35
0.42
0.25

Grapes, fresh+juice+wine
TOTALZ=2271
TOTALFREQ=1

107, 0.0015

Grapes, raisins
TOTALNZ=1
TOTALZ=8185
TOTALFREQ=1
36, 0.0015
0.420

Peaches, fresh
TOTALNZ=1
TOTALZ=117941
TOTALFREQ=1
58, 0.0015
0.130

Pears, fresh
TOTALZ=143247
TOTALFREQ=1

86, 0.0015

Plums, fresh
TOTALNZ=1
TOTALZ=34647
TOTALFREQ=1
58, 0.0015
0.130

Attachment 2. Acute Dietary Analysis using Endpoint for General U.S. Population
(including all subgroups)

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DEEM Acute analysis for PHOSALONE

1989-92 data

Residue file name: C:\Phosalone\Phosalone-Acute-Gen Pop. R96

Adjust. #2 used

Analysis Date 10-25-1999

Residue file dated:

10-25-1999/10:14:18/8

Reference dose: aRfD = 0.03 mg/kg bw/day NOAEL = 10 mg/kg bw/day

Comment: General U.S. Population Including All Subgroups

RDF indices and file names for Monte Carlo Analysis

- 1 almonds.rdf
- 2 apples.rdf
- 3 apple juice.rdf
- 4 apricots.rdf
- 5 cherries.rdf
- 6 grapes.rdf
- 7 grapesraisins.rdf
- 8 peaches.rdf
- 9 pears.rdf
- 10 plums.rdf

Food Crop	RESIDUE	RDF	
Adj. FactorsCode			
Grp Food Name	(ppm)	#	#1
#2			
-----	-----	-----	-----
13 0 Grapes	1.000000	6	1.000
1.000 FDA data			
Full comment: FDA data			
14 0 Grapes-raisins	1.000000	7	1.000
1.000 FDA data			
Full comment: FDA data			
15 0 Grapes-juice	1.000000	6	1.200
1.000 FDA data			
Full comment: FDA data			

40 14 Almonds	1.000000	1	1.000
1.000 FT dat			
Full comment: FT data			
52 11 Apples			
11- Uncooked	1.000000	2	1.000
1.000 FDA da			
Full comment: FDA data			
12- Cooked: NFS	1.000000	2	1.000
1.000 FDA da			
Full comment: FDA data			
13- Baked	1.000000	2	1.000
1.000 FDA da			
Full comment: FDA data			
14- Boiled	1.000000	2	1.000
1.000 FDA da			
Full comment: FDA data			
15- Fried	1.000000	2	1.000
1.000 FDA da			
Full comment: FDA data			
18- Dried	0.000130	0	1.000
1.000 FDA da			
Full comment: FDA data			
31- Canned: NFS	1.000000	2	0.300
1.000 FDA da			
Full comment: FDA data			
32- Canned: Cooked	1.000000	2	0.300
1.000 FDA da			
Full comment: FDA data			
33- Canned: Baked	1.000000	2	0.300
1.000 FDA da			
Full comment: FDA data			
34- Canned: Boiled	1.000000	2	0.300
1.000 FDA da			
Full comment: FDA data			
42- Frozen: Cooked	1.000000	2	1.000
1.000 FDA da			
Full comment: FDA data			
53 11 Apples- dried	1.000000	2	8.000
1.000 FDA da			
Full comment: FDA data			
54 11 Apples- juice/cider	1.000000	3	1.000
1.000 FDA da			

Full comment: FDA data			
56 11 Pears			
11-Uncooked	1.000000	9	1.000
1.000 FDA da			
Full comment: FDA data			
12-Cooked: NFS	1.000000	9	1.000
1.000 FDA da			
Full comment: FDA data			
13-Baked	1.000000	9	1.000
1.000 FDA da			
Full comment: FDA data			
14-Boiled	1.000000	9	1.000
1.000 FDA da			
Full comment: FDA data			
31-Canned: NFS	1.000000	9	0.300
1.000 FDA da			
Full comment: FDA data			
57 11 Pears-dried	1.000000	9	6.250
1.000 FDA da			
Full comment: FDA data			
59 12 Apricots	1.000000	4	1.000
1.000 Transl			
Full comment: Translated FDA data from peaches			
60 12 Apricots-dried	1.000000	4	6.000
1.000 Transl			
Full comment: Translated FDA data from peaches			
61 12 Cherries	1.000000	5	1.000
1.000 FT dat			
Full comment: FT data with Canadian MRL			
62 12 Cherries-dried	1.000000	5	4.000
1.000 FT dat			
Full comment: FT data with Canadian MRL			
63 12 Cherries-juice	1.000000	5	1.500
1.000 FT dat			
Full comment: FT data with Canadian MRL			
65 12 Peaches			
11-Uncooked	1.000000	8	1.000
1.000 FDA da			
Full comment: FDA data			
12-Cooked: NFS	1.000000	8	1.000
1.000 FDA da			
Full comment: FDA data			

13- Baked	1. 000000	8	1. 000
1. 000 FDA da			
Full comment: FDA data			
14- Boiled	1. 000000	8	1. 000
1. 000 FDA da			
Full comment: FDA data			
31- Canned: NFS	1. 000000	8	0. 300
1. 000 FDA da			
Full comment: FDA data			
41- Frozen: NFS	1. 000000	8	1. 000
1. 000 FDA da			
Full comment: FDA data			
66 12 Peaches- dried	1. 000000	8	7. 000
1. 000 FDA da			
Full comment: FDA data			
67 12 Plums (damsons)			
11- Uncooked	1. 000000	10	1. 000
1. 000 Transl			
Full comment: Translated FDA data from peaches			
12- Cooked: NFS	1. 000000	10	1. 000
1. 000 Transl			
Full comment: Translated FDA data from peaches			
31- Canned: NFS	1. 000000	10	0. 300
1. 000 Transl			
Full comment: Translated FDA data from peaches			
42- Frozen: Cooked	1. 000000	10	1. 000
1. 000 Transl			
Full comment: Translated FDA data from peaches			
51- Cured: NFS (smoked/p	1. 000000	10	1. 000
1. 000 Transl			
Full comment: Translated FDA data from peaches			
68 12 Plums- prunes (dried)	1. 000000	10	5. 000
1. 000 Transl			
Full comment: Translated FDA data from peaches			
69 12 Plums/prune- juice	1. 000000	10	1. 400
1. 000 Transl			
Full comment: Translated FDA data from peaches			
315 0 Grapes- wine and sherry	1. 000000	6	1. 000
1. 000 FDA da			
Full comment: FDA data			
377 11 Apples- juice- concentrate	1. 000000	3	3. 000
1. 000 FDA da			

Full comment: FDA data			
392 0	Grapes-juice-concentrate	1.000000	6 3.600
1.000 FDA da			
Full comment: FDA data			
402 12	Peaches-juice	1.000000	8 1.000
1.000 FDA da			
Full comment: FDA data			
404 11	Pears-juice	1.000000	9 1.000
1.000 FDA da			
Full comment: FDA data			
410 12	Apricot juice	1.000000	4 1.000
1.000 Transl			
Full comment: Translated FDA data from peaches			

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DEEM ACUTE analysis for PHOSALONE

(1989-92 data)

Residue file: Phosalone-Acute-Gen Pop. R96

Adjustment

factor #2 used.

Analysis Date: 10-25-1999/10:53:13

Residue file dated:

10-25-1999/10:14:18/8

Acute Reference Dose (aRfD) = 0.030000 mg/kg body-wt/day

NOAEL (Acute) = 10.000000 mg/kg body-wt/day

MC iterations = 1000 MC list in residue file MC seed = 0

Run Comment: General U.S. Population Including All Subgroups

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Summary calculations:

95th Percentile			99th Percentile			
99.9th Percentile						
Exposure	% aRfD	MDE	Exposure	% aRfD	MDE	Exposure
% aRfD	MDE					

U. S. pop - all seasons:						
0.000000	0.00	>1000000	0.000004	0.01	>1000000	
0.000049	0.16	205270				
All infants (<1 year):						
0.000000	0.00	>1000000	0.000024	0.08	418197	
0.000084	0.28	119371				
Nursing infants (<1 year):						
0.000000	0.00	>1000000	0.000014	0.05	717306	
0.000094	0.31	106007				
Non-nursing infants (<1 yr):						
0.000004	0.01	>1000000	0.000025	0.08	395666	
0.000065	0.22	152943				
Children (1-6 years):						
0.000002	0.01	>1000000	0.000026	0.09	383455	
0.000221	0.74	45281				
Children (7-12 years):						
0.000000	0.00	>1000000	0.000009	0.03	>1000000	
0.000132	0.44	75869				
Females (13+/preg/not nsg):						
0.000000	0.00	>1000000	0.000006	0.02	>1000000	
0.000082	0.27	121987				
Females (13+/nursing):						
0.000000	0.00	>1000000	0.000007	0.02	>1000000	
0.000080	0.27	124892				
Females (13- 19 yrs/np/nn):						
0.000000	0.00	>1000000	0.000001	0.00	>1000000	
0.000012	0.04	802844				
Females (20+ years/np/nn):						
0.000000	0.00	>1000000	0.000002	0.01	>1000000	
0.000017	0.06	582953				
Females (13- 50 years):						
0.000000	0.00	>1000000	0.000002	0.01	>1000000	
0.000016	0.05	635951				
Males (13- 19 years):						

0.000000	0.00	>1000000	0.000001	0.00	>1000000
0.000014	0.05	725863			
Males (20+ years):					
0.000000	0.00	>1000000	0.000001	0.00	>1000000
0.000017	0.06	602010			

Attachment 3. Acute Dietary Analysis using Endpoint for Females 13+ Years

U. S. Environmental Protection Agency

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DEEM Acute analysis for PHOSALONE

1989-92 data

Residue file name: C:\Phosalone\Phosalone-Acute-Females

13+.R96Adj ust. #2 used

Analysis Date 10-25-1999

Residue file dated:

10-21-1999/08:44:11/8

Reference dose: aRfD = 0.01 mg/kg bw/day NOAEL = 1 mg/kg bw/day

Comment: Females 13+ Subgroups

RDF indices and file names for Monte Carlo Analysis

- 1 almonds.rdf
- 2 apples.rdf
- 3 apple juice.rdf
- 4 apricots.rdf
- 5 cherries.rdf
- 6 grapes.rdf
- 7 grapesraisins.rdf
- 8 peaches.rdf
- 9 pears.rdf
- 10 plums.rdf

Food Crop	RESIDUE	RDF	
Adj. FactorsCode	(ppm)	#	#1
Grp Food Name			
#2			
13 0 Grapes	1.000000	6	1.000
1.000 FDA da			
Full comment: FDA data			
14 0 Grapes-raisins	1.000000	7	1.000
1.000 FDA da			
Full comment: FDA data			
15 0 Grapes-juice	1.000000	6	1.200
1.000 FDA da			
Full comment: FDA data			
40 14 Almonds	1.000000	1	1.000

1.000 FT dat			
Full comment: FT data			
52 11 Apples			
11-Uncooked	1.000000	2	1.000
1.000 FDA da			
Full comment: FDA data			
12-Cooked: NFS	1.000000	2	1.000
1.000 FDA da			
Full comment: FDA data			
13-Baked	1.000000	2	1.000
1.000 FDA da			
Full comment: FDA data			
14-Boiled	1.000000	2	1.000
1.000 FDA da			
Full comment: FDA data			
15-Fried	1.000000	2	1.000
1.000 FDA da			
Full comment: FDA data			
18-Dried	0.000130	0	1.000
1.000 FDA da			
Full comment: FDA data			
31-Canned: NFS	1.000000	2	0.300
1.000 FDA da			
Full comment: FDA data			
32-Canned: Cooked	1.000000	2	0.300
1.000 FDA da			
Full comment: FDA data			
33-Canned: Baked	1.000000	2	0.300
1.000 FDA da			
Full comment: FDA data			
34-Canned: Boiled	1.000000	2	0.300
1.000 FDA da			
Full comment: FDA data			
42-Frozen: Cooked	1.000000	2	1.000
1.000 FDA da			
Full comment: FDA data			
53 11 Apples-dried	1.000000	2	8.000
1.000 FDA da			
Full comment: FDA data			
54 11 Apples-juice/cider	1.000000	3	1.000
1.000 FDA da			
Full comment: FDA data			

56 11	Pears			
	11-Uncooked	1.000000	9	1.000
1.000	FDA da			
	Full comment: FDA data			
	12-Cooked: NFS	1.000000	9	1.000
1.000	FDA da			
	Full comment: FDA data			
	13-Baked	1.000000	9	1.000
1.000	FDA da			
	Full comment: FDA data			
	14-Boiled	1.000000	9	1.000
1.000	FDA da			
	Full comment: FDA data			
	31-Canned: NFS	1.000000	9	0.300
1.000	FDA da			
	Full comment: FDA data			
57 11	Pears-dried	1.000000	9	6.250
1.000	FDA da			
	Full comment: FDA data			
59 12	Apricots	1.000000	4	1.000
1.000	Transl			
	Full comment: Translated FDA data from peaches			
60 12	Apricots-dried	1.000000	4	6.000
1.000	Transl			
	Full comment: Translated FDA data from peaches			
61 12	Cherries	1.000000	5	1.000
1.000	FT dat			
	Full comment: FT data with Canadian MRL			
62 12	Cherries-dried	1.000000	5	4.000
1.000	FT dat			
	Full comment: FT data with Canadian MRL			
63 12	Cherries-juice	1.000000	5	1.500
1.000	FT dat			
	Full comment: FT data with Canadian MRL			
65 12	Peaches			
	11-Uncooked	1.000000	8	1.000
1.000	FDA da			
	Full comment: FDA data			
	12-Cooked: NFS	1.000000	8	1.000
1.000	FDA da			
	Full comment: FDA data			
	13-Baked	1.000000	8	1.000

1.000 FDA da			
Full comment: FDA data			
14-Boiled	1.000000	8	1.000
1.000 FDA da			
Full comment: FDA data			
31-Canned: NFS	1.000000	8	0.300
1.000 FDA da			
Full comment: FDA data			
41-Frozen: NFS	1.000000	8	1.000
1.000 FDA da			
Full comment: FDA data			
66 12 Peaches-dried	1.000000	8	7.000
1.000 FDA da			
Full comment: FDA data			
67 12 Plums (damsons)			
11-Uncooked	1.000000	10	1.000
1.000 Transl			
Full comment: Translated FDA data from peaches			
12-Cooked: NFS	1.000000	10	1.000
1.000 Transl			
Full comment: Translated FDA data from peaches			
31-Canned: NFS	1.000000	10	0.300
1.000 Transl			
Full comment: Translated FDA data from peaches			
42-Frozen: Cooked	1.000000	10	1.000
1.000 Transl			
Full comment: Translated FDA data from peaches			
51-Cured: NFS (smoked/p	1.000000	10	1.000
1.000 Transl			
Full comment: Translated FDA data from peaches			
68 12 Plums-prunes (dried)	1.000000	10	5.000
1.000 Transl			
Full comment: Translated FDA data from peaches			
69 12 Plums/prune-juice	1.000000	10	1.400
1.000 Transl			
Full comment: Translated FDA data from peaches			
315 0 Grapes-wine and sherry	1.000000	6	1.000
1.000 FDA da			
Full comment: FDA data			
377 11 Apples-juice-concentrate	1.000000	3	3.000
1.000 FDA da			
Full comment: FDA data			

392 0	Grapes-juice-concentrate	1.000000	6	3.600
1.000	FDA da			
	Full comment: FDA data			
402 12	Peaches-juice	1.000000	8	1.000
1.000	FDA da			
	Full comment: FDA data			
404 11	Pears-juice	1.000000	9	1.000
1.000	FDA da			
	Full comment: FDA data			
410 12	Apricot juice	1.000000	4	1.000
1.000	Transl			
	Full comment: Translated FDA data from peaches			

U. S. Environmental Protection Agency

Ver. 6.78

DEEM ACUTE analysis for PHOSALONE

(1989-92 data)

Residue file: Phosalone-Acute-Females 13+. R96

Adjustment

factor #2 used.

Analysis Date: 10-25-1999/12:00:20

Residue file dated:

10-25-1999/11:45:09/8

Acute Reference Dose (aRfD) = 0.010000 mg/kg body-wt/day

NOAEL (Acute) = 1.000000 mg/kg body-wt/day

MC iterations = 1000

MC list in residue file

MC seed =

0

Run Comment: Females 13+ Subgroups

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Summary calculations:

95th Percentile			99th Percentile			
99.9th Percentile						
Exposure	% aRfD	MDE	Exposure	% aRfD	MDE	Exposure
% aRfD	MDE					

Females (13+/preg/not nsg):						
0.000000	0.00	>1000000	0.000006	0.06	169444	
0.000052	0.52	19301				
Females (13+/nursing):						
0.000000	0.00	>1000000	0.000007	0.07	143123	
0.000073	0.73	13743				
Females (13-19 yrs/np/nn):						
0.000000	0.00	>1000000	0.000001	0.01	857950	
0.000012	0.12	80115				
Females (20+ years/np/nn):						
0.000000	0.00	>1000000	0.000002	0.02	493395	
0.000017	0.17	58014				
Females (13-50 years):						
0.000000	0.00	>1000000	0.000002	0.02	532455	
0.000017	0.17	60551				

Attachment 4. Chronic (Non-cancer) Dietary Analysis

U. S. Environmental Protection Agency

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DEEM Chronic analysis for PHOSALONE

1989-92 data

Residue file: C:\Phosalone\Phosalone-Chronic.R96

Adjust. #2 used

Analysis Date 11-01-1999

Residue file dated:

11-01-1999/07:53:50/8

Reference dose (RfD) = 0.002 mg/kg bw/day

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Food Crop                               RESIDUE
Adj. Factors  Comment
Code  Grp  Food Name                    (ppm)                #1
#2
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13 0    Grapes                        0.000067             1.000
1.000 FDA data
Full comment: FDA data
14 0    Grapes-raisins                0.000058             1.000
1.000 FDA data
Full comment: FDA data
15 0    Grapes-juice                  0.000067             1.200
1.000 FDA data
Full comment: FDA data
40 14   Almonds                       0.000001             1.000
1.000 FT data
Full comment: FT data
52 11   Apples
      11-Uncooked                      0.000130             1.000
1.000 FDA data
Full comment: FDA data
      12-Cooked: NFS                    0.000130             1.000
1.000 FDA data
Full comment: FDA data
      13-Baked                          0.000130             1.000
1.000 FDA data
Full comment: FDA data

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14- Boiled	0. 000130	1. 000
1. 000 FDA da		
Full comment: FDA data		
15- Fried	0. 000130	1. 000
1. 000 FDA da		
Full comment: FDA data		
18- Dried	0. 000130	1. 000
1. 000 FDA da		
Full comment: FDA data		
31- Canned: NFS	0. 000130	0. 300
1. 000 FDA da		
Full comment: FDA data		
32- Canned: Cooked	0. 000130	0. 300
1. 000 FDA da		
Full comment: FDA data		
33- Canned: Baked	0. 000130	0. 300
1. 000 FDA da		
Full comment: FDA data		
34- Canned: Boiled	0. 000130	0. 300
1. 000 FDA da		
Full comment: FDA data		
42- Frozen: Cooked	0. 000130	1. 000
1. 000 FDA da		
Full comment: FDA data		
53 11 Apples- dried	0. 000130	8. 000
1. 000 FDA da		
Full comment: FDA data		
54 11 Apples-juice/ci der	0. 000210	1. 000
1. 000 FDA da		
Full comment: FDA data		
56 11 Pears		
11- Uncooked	0. 000001	1. 000
1. 000 FDA da		
Full comment: FDA data		
12- Cooked: NFS	0. 000001	1. 000
1. 000 FDA da		
Full comment: FDA data		
13- Baked	0. 000001	1. 000
1. 000 FDA da		
Full comment: FDA data		
14- Boiled	0. 000001	1. 000
1. 000 FDA da		

Full comment: FDA data		
31-Canned: NFS	0. 000001	0. 300
1. 000 FDA da		
Full comment: FDA data		
57 11 Pears-dried	0. 000001	6. 250
1. 000 FDA da		
Full comment: FDA data		
59 12 Apricots	0. 000014	1. 000
1. 000 Transl		
Full comment: Translated FDA data from peaches		
60 12 Apricots-dried	0. 000014	6. 000
1. 000 Transl		
Full comment: Translated FDA data from peaches		
61 12 Cherries	0. 016000	1. 000
1. 000 FT dat		
Full comment: FT data with Canadian MRL		
62 12 Cherries-dried	0. 016000	4. 000
1. 000 FT dat		
Full comment: FT data with Canadian MRL		
63 12 Cherries-juice	0. 016000	1. 500
1. 000 FT dat		
Full comment: FT data with Canadian MRL		
65 12 Peaches		
11-Uncooked	0. 000002	1. 000
1. 000 FDA da		
Full comment: FDA data		
12-Cooked: NFS	0. 000002	1. 000
1. 000 FDA da		
Full comment: FDA data		
13-Baked	0. 000002	1. 000
1. 000 FDA da		
Full comment: FDA data		
14-Boiled	0. 000002	1. 000
1. 000 FDA da		
Full comment: FDA data		
31-Canned: NFS	0. 000002	0. 300
1. 000 FDA da		
Full comment: FDA data		
41-Frozen: NFS	0. 000002	1. 000
1. 000 FDA da		
Full comment: FDA data		
66 12 Peaches-dried	0. 000002	7. 000

1.000 FDA da		
Full comment: FDA data		
67 12 Plums (damsons)		
11-Uncooked	0.000006	1.000
1.000 Transl		
Full comment: Translated FDA data from peaches		
12-Cooked: NFS	0.000006	1.000
1.000 Transl		
Full comment: Translated FDA data from peaches		
31-Canned: NFS	0.000006	0.300
1.000 Transl		
Full comment: Translated FDA data from peaches		
42-Frozen: Cooked	0.000006	1.000
1.000 Transl		
Full comment: Translated FDA data from peaches		
51-Cured: NFS (smoked/pickled/salted)	0.000006	1.000
1.000 Transl		
Full comment: Translated FDA data from peaches		
68 12 Plums-prunes (dried)	0.000006	5.000
1.000 Transl		
Full comment: Translated FDA data from peaches		
69 12 Plums/prune-juice	0.000006	1.400
1.000 Transl		
Full comment: Translated FDA data from peaches		
315 0 Grapes-wine and sherry	0.000067	1.000
1.000 FDA da		
Full comment: FDA data		
377 11 Apples-juice-concentrate	0.000210	3.000
1.000 FDA da		
Full comment: FDA data		
392 0 Grapes-juice-concentrate	0.000067	3.600
1.000 FDA da		
Full comment: FDA data		
402 12 Peaches-juice	0.000002	1.000
1.000 FDA da		
Full comment: FDA data		
404 11 Pears-juice	0.000001	1.000
1.000 FDA da		
Full comment: FDA data		
410 12 Apricot juice	0.000014	1.000
1.000 Transl		

Full comment: Translated FDA data from peaches

U. S. Environmental Protection Agency

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DEEM Chronic analysis for PHOSALONE

(1989-92 data)

Residue file name: C:\Phosalone\Phosalone-Chronic.R96

Adjustment

factor #2 used.

Analysis Date 11-01-1999/07:55:58

Residue file dated:

11-01-1999/07:53:50/8

Reference dose (RfD, CHRONIC) = .002 mg/kg bw/day

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Total exposure by population subgroup

		Total
Exposure		
Percent of Rfd	Population Subgroup	mg/kg body wt/day
U. S. Population (total) 0.0%		0.000001
U. S. Population (spring season) 0.0%		0.000001
U. S. Population (summer season) 0.0%		0.000000
U. S. Population (autumn season) 0.0%		0.000001
U. S. Population (winter season) 0.0%		0.000000
Northeast region 0.0%		0.000001
Midwest region 0.0%		0.000001
Southern region 0.0%		0.000000
Western region 0.0%		0.000001
Hispanics 0.0%		0.000000
Non-hispanic whites 0.0%		0.000001
Non-hispanic blacks 0.0%		0.000000
Non-hispanic/non-white/non-black) 0.0%		0.000001

All infants (< 1 year)	0.000001
0.1%	
Nursing infants	0.000001
0.0%	
Non-nursing infants	0.000001
0.1%	
Children 1-6 yrs	0.000002
0.1%	
Children 7-12 yrs	0.000001
0.0%	
Females 13-19(not preg or nursing)	0.000000
0.0%	
Females 20+ (not preg or nursing)	0.000000
0.0%	
Females 13-50 yrs	0.000000
0.0%	
Females 13+ (preg/not nursing)	0.000000
0.0%	
Females 13+ (nursing)	0.000001
0.1%	
Males 13-19 yrs	0.000000
0.0%	
Males 20+ yrs	0.000000
0.0%	
Seniors 55+	0.000000
0.0%	
Pacific Region	0.000001
0.0%	
